BUREAU VERITAS
Certification

TRIWORKS GROUP S.R.L.

Via Leone Belpulsi, 3 - 86100 Campobasso (CB) - ITALY

Certified site:

Via Don Giuseppe Mucciardi, 5 - 86020 Campochiaro (CB) - ITALY

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC as amended

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product subcategory :	Devices for stimulation or inhibition
Generic group:	See Annex
Model:	See Annex
Class:	See Annex

(may refer to the Annex of the certificate that lists all the products / models of devices subject to certification)

Reference BV practice: ZIG. N. 60565036

Original cycle start date: **20/09/2018**

Expiry date of previous cycle: **NA**

Certification / Recertification Audit date: **09/08/2018**

Certification / Recertification cycle start date: **20/09/2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **19/09/2021**

Certificate No. - Version: IT285733 - 3

Revision date: **07/08/2020**

ANDREA FILIPPI – Certification SL Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347- 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

BUREAU VERITAS
Certification

Annex to the CE Certificate n° IT285733

Product subcategory :	Devices for stimulation or inhibition
Generic group:	Medical device for diathermy
Model:	MEDICAL RF (BRF3S-A); MEDICAL RF (BRF3-A); DIATEC (DT3S-A); DIATEC (DT3-A).
Class:	IIb
Generic group:	Plasma electrosurgical medical device
Model:	AGE JET
Class:	IIb
Generic group:	High-Intensity Focused Ultrasound medical device
Model:	Sideria
Class:	IIb

Reference BV practice: ZIG. N. 60565036

Original cycle start date: **20/09/2018**

Expiry date of previous cycle: **NA**

Certification / Recertification Audit date: **09/08/2018**

Certification / Recertification cycle start date: **20/09/2018**

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Certification

Annex to the CE Certificate n° IT285733

Product subcategory :	Devices for stimulation or inhibition
Generic group:	Medical device for low frequency ultrasound cavitation and radiofrequency
Model:	OMNIKA (CR1-A), OMNIKA (CR1S-A)
Class:	IIb
Generic group:	Cavitation and Radio Frequency medical device
Model:	Synetica Evolution
Class:	IIb
Generic group:	Medical device for electrical stimulation neuromuscular
Model:	MYRIA
Class:	IIb

Reference BV practice: ZIG. N. 60565036

Original cycle start date: **20/09/2018**

Expiry date of previous cycle: **NA**

Certification / Recertification Audit date: **09/08/2018**

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